

REMARKS

Upon entry of the present amendment, the claims in the application the claims in the application remain claims 1-11 and 13-21, of which claims 1 and 4 are independent.

Independent claims 1 and 4 are amended to further define that the calibration equation is determined in advance from a spectrum measured using a receptacle with the same specifications as the blood collection receptacle, and to (again) define that the detected light is at least one of diffusely reflected light, diffusely transmitted light and diffusely transmitted and reflected light from the blood sample. Claim 3 is amended to define that the chemometrics technique is selected from the group consisting of the identified techniques. New claims 14-19 are added to define that multiple different object characteristics of the blood sample are determined, and that the blood sample receptacle has an optical path length of 1-2 cm.

Applicant respectfully submits that the above amendments are fully supported by the original disclosure, including the original claims, the discussion at page 1, lines 6-10, page 2, lines 4-24, page 6, lines 18 - 25, and page 9, lines 5-10. Applicant further respectfully submits that no new matter is introduced by the above amendments.

Further, applicant respectfully submits that the amendment to claim 3 overcomes the Examiner's rejection of the claim under 35 USC §112, second paragraph, set forth at item 1 of the Office Action, and it is respectfully requested that such rejection be reconsidered and withdrawn.

Rejection Under 35 USC §102(b)

The Examiner has rejected claims 1-7 and 9-13 under 35 USC §102(b) as being anticipated Soller et al. (US Patent 6,006,119), set forth at item 2 of the Office Action. It is essentially the Examiner's position that all of the features of the claimed analytical method and apparatus are expressly or inherently disclosed by Soller.

Applicant's Response

Upon careful consideration, and in light of the above amendments to claims 1 and 4, applicant respectfully submits that such rejection is overcome and that each of the present claims is clearly patentably distinct over the Soller reference, based on the following.

Initially, applicant respectfully submits that Soller's method and apparatus for measuring blood hematocrit does not involve or make obvious the feature of amended claims 1 and 4 that the calibration equation has been determined in advance from a spectrum measured *using a receptacle with the same specifications as said blood collection receptacle* relative to blood specimens with known object characteristics for thereby determining an object characteristic of the blood sample. The receptacle according to the invention may be an ordinary tube or bag (see claims 10, 13) and has an optical path length of 1-2 cm (see claims 16, 19).

In contrast, Soller's method and apparatus for in vitro testing of blood samples involves use of a quartz cuvette (see item 1061 in his Fig. 14A), corresponding to the special crystal sample cell discussed at page 2, lines 13-24 of the present specification, and each sample (whether a reference sample or a tested/unknown sample) is contained in the same quartz cuvette.

Applicant respectfully submits that the discussed distinctions are very significant as a practical matter. Even though using a quartz cuvette, as disclosed by Soller, to house a given sample is effective, allowing for determination of an accurate calibration equation and sample measurements, the calibration and sample measurements effected using a plurality of ordinary, interchangeable tubes or bags with the same specifications (the difference in absorbance can be compensated) according to the claimed invention can achieve a useful and substantially accurate analysis. On the other hand, if the special cuvette is broken by accident or otherwise, then time, labor and added expense are required to adjust the calibration equation to a new cell for continuing an analysis. Also, as a practical matter, the special cuvette cannot be used in an agricultural or factory environment due to the large number of sample objects to be analyzed in such an environment. Since the apparatus according to the present invention uses a plurality of interchangeable (ordinary, inexpensive) test tubes or sample bags, a broken test tube or sample bag can be quickly and easily replaced without need for recalibration, and the apparatus can be efficiently used for quick analyses of liquids in an agricultural or factory environment by an unskilled operator, where such type of analysis is required. See page 9, lines 5-10 of the original specification.

Relatedly, new claims 14-16 and 18-20, again, define that multiple object characteristics of the liquid are determined in the method and apparatus of the invention. This is different from the teaching of Soller, in which only a single object characteristic, blood hematocrit, is measured.

Based on the foregoing, applicant respectfully submits that the rejection of claims 1-7 and 9-13 under 35 USC 102(b) as unpatentable over Soller et al. is overcome, and accordingly it is respectfully requested that such rejection be reconsidered and withdrawn.

Rejection Under 35 USC §103(a)

The Examiner has also rejected claim 8 under 35 USC §103(a) as being unpatentable over Soller et al. In view of Chiaken et al. (US Patent 6,293,686), set forth at item 4 of the Office Action. It is the Examiner's position that while Soller does not teach a temperature control means as defined in claim 8, it would have been obvious at the time of the invention to provide Soller's method and apparatus with such a temperature control means based on the teachings of Chiaken.

Applicant's Response

Upon careful consideration, and in light of the above amendments to claim 4, applicant respectfully submits that such rejection is overcome and that present claim 8 is clearly patentably distinct over the applied references, based on the foregoing arguments regarding the deficiencies of Soller relative to claim 4 (which are not overcome by any additional teaching of Chiaken), and because the proposed modification of Soller's apparatus relative to a select teaching of the Chiaken reference, as proposed by the Examiner is improperly based on a suggestion coming entirely from the Examiner, rather than from any teaching or suggestion which may be fairly gleaned from the references themselves.

Relative to the proposed modification/combination, Chiaken discloses a feature of thermal tissue modulation used in relation to noninvasive spectroscopic measurement of analytes such as glucose involving, for example, a person's finger or other tissue. The thermal tissue modulation is disclosed as solving problems unique to noninvasive spectroscopic measurement of analytes through tissue. On the other hand, while Soller discloses both in vivo and in vitro



measurement of hematocrit, the aspect of Soller's disclosure applied in rejecting the present claims strictly involves in vitro measurement of blood samples contained in a receptacle such as a tube or bag. Correspondingly, applicant respectfully submits that persons skilled in the art would not consider it obvious to combine/modify Soller's in vitro measurement apparatus with Chiaken's thermal tissue modulation because the references do not provide any motivation for doing so, e.g., the reasons discussed by Chiaken all involve special characteristics of tissue, and hence do not apply to Soller's in vitro measurement apparatus.

Based on the foregoing, applicant respectfully submits that the rejection of claims 2-3 under 35 USC §103(a) based on the Soller and Chiaken patents is overcome, and accordingly it is respectfully requested that the rejection be reconsidered and withdrawn.

Other References Cited in the Office Action

The additional references cited by the Examiner on the Form PTO-892 attached to the Office Action (Mehdelson et al., Messerschmidt, Haaland, Malin et al., Kobayashi et al., Berger et al., and Maruo et al.) have been considered by applicant, but it is respectfully submitted that these additional references fail to overcome the deficiencies of the Soller and Chiaken references as discussed above relative to the claimed invention.

New Claims

New claims 14-21 are believed to be allowable over the references of record based on the foregoing arguments regarding the merits of claims 1 and 4, as well as on the merits of the additional features recited therein.

Conclusion

In conclusion, applicant has overcome the Examiner's rejections as presented in the Office Action; and moreover, applicant has considered all of the references of record, and it is respectfully submitted that the invention as defined by each of the present claims is clearly patentably distinct thereover.

The application is now believed to be in condition for allowance, and a notice to this effect is earnestly solicited.

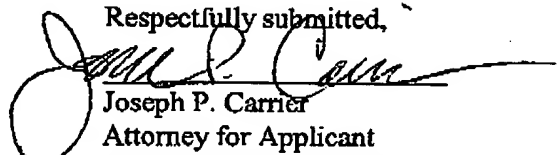
If the Examiner is not fully convinced of all of the claims now in the application, applicant

respectfully requests that the Examiner telephonically contact applicant's undersigned representative to expeditiously resolve prosecution of the application.

Favorable reconsideration is respectfully requested.

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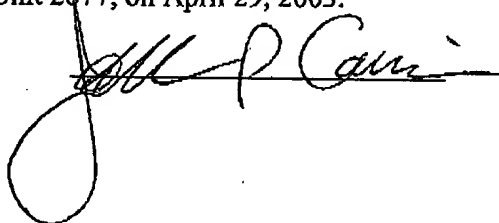
Respectfully submitted,


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